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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,536	01/29/2001	William H.R. Langridge	12273-3	9620

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Sheldon & Mak
c/o David A. Farah, M.D.
9th Floor
225 South Lake Avenue
Pasadena, CA 91101

EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,536	LANGRIDGE ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50- 53, 55- 71, and 73- 86* is/are pending in the application.

4a) Of the above claim(s) *65- 68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50- 53, 55-64, 69- 71, and 73- 86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to paper filed 4 May 2004.

Claims 50- 53, 55-64, 69- 71, and 73- 86 are under consideration.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 50- 54 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Applicant has amended the claims clarify the meanings of the disease and the parts of the cholera toxin.

The rejection of claims 50- 64 and 69- 86 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain antigens including cholera, E. *coli*, and rotavirus, does not reasonably provide enablement for immunogenic antigens of all mammalian diseases that elicits a protective immune response is withdrawn.

Applicant has amended the claims to "infectious" mammalian disease, which means bacteria or virus and not diseases caused by non-infectious pathogens.

Claim Rejections - 35 USC § 102

Claims 50 and 63 were rejected under 35 U.S.C. 102(b) as being anticipated by Arakawa *et al.*

Applicant has amended the claims to exclude the fusion protein as taught by Arakawa *et al.* because the immunogen of Arakawa *et al.* linked to the cholera toxin subunit is not from an infectious pathogen.

Rejections Maintained

Claim Rejections - 35 USC § 103

Claims 50, 51, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arakawa *et al.* and Gonzalez *et al.*

Applicant agues all the 103 rejections together based on the Arakawa *et al.* reference.

Applicant argues that over Arakawa *et al.* teach a different immune response and immunosuppression, that no one of ordinary skill in the art would have any reason to suspect a CTB fusion protein to generate an immune response, that one of ordinary skill in the art would expect the opposite response, and thus there is no reason to combine.

Applicant's arguments have been fully considered and not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teachings of Gonzalez *et al.* and the other art cited shows the skill in the art.

It is noted that Arakawa *et al.* does not teach only what applicant argues but also shows that CTB is an adjuvant and does result in an increased immune response (see at least Figures 4 A and B).

Gonzalez *et al.* clearly teach that CTB is an effective immunogen and mucosal adjuvant and can be used as a fusion protein (page 227, column 2).

Arakawa *et al.* provides structure of the fusion protein with a 3 prime fusion.

Therefore, the instant invention is obvious over Arakawa *et al.* and Gonzalez *et al.*

Claims 50 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arakawa *et al.* and Gonzalez *et al.* as applied to claim 50, 51, and 58 above, in view of Manson *et al.* (TIBTECH September 1995 vol. 13: 388- 392).

Applicant agues all the 103 rejections together based on the Arakawa *et al.* reference as discussed in the rejection directly above.

Applicant's arguments have been fully considered and not found persuasive.

The rejection is maintained because Arakawa *et al.* does not teach away as discussed above and with one of ordinary skill in the art at the time of invention would have known the use of CTB and the structures that can be used make fusion proiteins.

Therefore, the instant invention is obvious over Arakawa *et al.* and Gonzalez *et al.* in view of Manson *et al.*

Claims 50, 51, 53- 57 and 58- 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arakawa *et al.* and Gonzalez *et al.* as applied to claims 50, 51 and 58 above, and further in view of Hajishengallis *et al.*

Applicant agues all the 103 rejections together based on the Arakawa *et al.* reference as discussed in the rejection of claims 50, 51, and 58 above.

Applicant's arguments have been fully considered and not found persuasive.

The rejection is maintained because Arakawa *et al.* does not teach away as discussed above and with one of ordinary skill in the art at the time of invention would have known the use of CTB and the structures that can be used make fusion proteins.

Therefore, the instant invention is obvious over Arakawa *et al.* and Gonzalez *et al.* in view of Hajishengallis *et al.*

Claims 50, 52, 64, and 69- 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arakawa *et al.* and Gonzalez *et al.* in view of Manson *et al.* as applied to claims 50 and 52 above, and further in view of Hajishengallis *et al.*

Applicant agues all the 103 rejections together based on the Arakawa *et al.* reference as discussed in the rejection of claims 50, 51, and 58 above.

Applicant's arguments have been fully considered and not found persuasive.

The rejection is maintained because Arakawa *et al.* does not teach away as discussed above and with one of ordinary skill in the art at the time of invention would have known the use of CTB and the structures that can be used make fusion proteins.

Therefore, the instant invention is obvious over Arakawa *et al.* and Gonzalez *et al.* in view of Gonzalez *et al.* and Hajishengallis *et al.*

New Rejection Based on Amendment

Claim Rejections - 35 USC § 103

Claim 63 rejected under 35 U.S.C. 103(a) as being unpatentable over Arakawa *et al.* and Gonzalez *et al.* as applied to claims 50, 51 and 58 above, and further in view of Hajishengallis *et al.*

The claim is drawn to a protein complex encoded by a DNA construct comprising 5 cholera toxin B fusion proteins with a 3 prime fusion of an infectious mammalian disease.

As discussed above and in arguments of record, the references teach a protein complex encoded by a DNA construct comprising 5 cholera toxin B fusion proteins with a 3 prime fusion of an infectious mammalian disease

Therefore, the instant invention is obvious over Arakawa *et al.* and Gonzalez *et al.* in view of Gonzalez *et al.* and Hajishengallis *et al.*

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Myron G. Hill
Patent Examiner
15 September 2004

JAMES HOUSEL 9/20/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600